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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,611	01/24/2002	Kornelia Polyak	001107.00224	6175

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BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER.
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1637

DATE MAILED: 03/31/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/053,611

Applicant(s)
POLYAK et al.

Examiner
Cynthia B Wilder

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 6, 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 29-53 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 29-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. Applicant's amendment filed in Paper No. 9 is acknowledged. Claims 1, 2, 29 and 31 have been amended. Claims 12-16 have been canceled and claims 33-53 have been added. All of the amendments and arguments have been thoroughly reviewed and considered but they are deemed moot in view of the new ground(s) of rejections. Any rejection not reiterated in this action have been withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

3. The prior art rejections under 35 USC 102(b) directed to claims 1, 9, 10, 29, 31 and 32 are withdrawn in view of Applicant's amendment. The prior art rejections under 35 USC 102/103 directed to claims 2, 3 12-16 are withdrawn in view of Applicant's amendment of the claims and cancellation of claims 12-16. The prior art rejections under 35 USC 103 directed to claims 4-8 , 11 and 30 are withdrawn in view of Applicant's amendment of the claims. The double patenting rejection is withdrawn for claims 12-16 in view of Applicant's cancellation of the claims. The double patenting rejection for claims 1-11 and 29-32 is maintained below.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re*

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Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. One again, Claims 1-11 and 29-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No.6,344,322 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '322 patent only slightly differs from the claimed invention in scope. For example, in the '322 patent the method to aid in detecting the presence of tumor cells in a patient comprises steps of identifying 12 specific single basepair mutations in a mitochondrial genome of a cell sample of a patient whereas the claims of the instant invention are not limited to any specific basepair mutations of the mitochondrial genome of a cell sample. The claims of the instant invention encompasses any single basepair mutations including those cited in the claims of the '322 patent. Thus, the difference in scope do not represent a patentable distinction.

New Ground(s) of Rejections

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Objections

4. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 4 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 1-11 and 29-53 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a method to aid in detecting the presence of tumor cells in a patient, comprising the steps of: determining the presence of a single basepair mutation in a mitochondrial genome of a cell sample of a patient, wherein the mutation is found in a tumor of the patient but not in normal tissues of the patient; and identifying the patient as having a tumor if one or more single basepair mutations are determined in the mitochondrial genome of the cell sample of the patient. The claims are also drawn to a method to aid in detecting the presence of tumor cells in a patient, comprising the steps of determining the presence of a single basepair mutation in a mitochondrial genome of a cell sample of a patient, wherein the mutation is

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found in a tumor of the patient but not in normal tissue of the patient and wherein the mutation has previously been identified as a somatic mutation in a tumor; and identifying the patient as having a tumor if one or more single basepair mutations are determined in the mitochondrial genome of the cell sample of the patient. The claims as written encompass a large genus of undisclosed single basepair mutations including somatic mutations of the mitochondrial genome not adequately described or disclosed in the specification. The specification at page 1 discloses that the human mitochondrial genome is a large, 16 kilobase circular double-stranded DNA. The specification further teaches in example 1 (pages 9-11) and Table 1 (page 17), the identification of 12 somatic mutations of the human mitochondrial DNA of human colorectal cancer cells. The specification however fails to describe or disclose a representative number of single basepairs mutations of the human mitochondrial DNA encompassed by the instant claims as written. The instant claims as written encompasses a plethora of single basepair mutations not disclosed or described anywhere in the specification. Additionally, it cannot be determined if any basepair mutation, besides those mentioned in Table 1, is capable of functioning in the method of determining the presence and absence of a tumor in a patient. A representative number of species for each genus must be disclosed to meet the written description requirement of 112, first paragraph. As set forth by the Court in *Vas Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date Applicant was in possession of the claimed invention. Absent a written description disclosing a representative number of the species as claimed in claims 1-11 and 29-53 of the specification fails to show that Applicant was, in fact, "in possession of the claimed invention" at the time the application for patent was filed.

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Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. One again, Claims 33-53 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-27 of U.S. Patent No.6,344,322 B1. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim(s) is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F. 3d 1428, 46 USPQ2d 1226 (fed.

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Cir. 1998); *In re Goodman*, 11 F. 3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of '322 patent only slightly differs from the claimed invention in scope. For example, in the '322 patent the method to aid in detecting the presence of tumor cells in a patient comprises steps of identifying 12 specific single basepair mutations in a mitochondrial genome of a cell sample of a patient whereas the claims of the instant invention are not limited to any specific basepair mutations of the mitochondrial genome of a cell sample. The claims of the instant invention encompasses any single basepair somatic mutations including those cited in the claims of the '322 patent. Thus, the difference in scope do not represent a patentable distinction.

Conclusion

9. No claims are allowed. However, the claims are free of the prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cynthia Wilder whose telephone number is (703) 305-1680. The examiner can normally be reached on Monday through Thursday from 9:30 am to 6:30 pm and on Friday from 9:30 am to 1:30 pm.

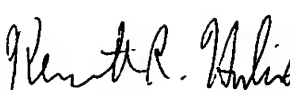
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (703) 308-1119. The official fax phone number for the Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group's receptionist at (703) 308-0196.

Cynthia B. Wilder, Ph.D.

March 25, 2003


KENNETH R. HORLICK, PH.D.
PRIMARY EXAMINER

3/26/03